UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	MDL No. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	Civil Action No. 01-CV-12257-PBS
)	Subcategory Case No. 06-CV-11069-PBS
THIS DOCUMENT RELATES TO)	
State of Arizona v. Abbott Labs., Inc., et al.,)	Hon. Patti B. Saris
06-CV-11069-PBS)	

DEFENDANTS ASTRAZENECA PHARMACEUTICALS LP AND ZENECA INC.'S INDIVIDUAL REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS THE PLAINTIFF STATE OF ARIZONA'S FIRST AMENDED COMPLAINT

Rather than meaningfully challenge AstraZeneca's arguments, Plaintiff relies on the incredible assertion that because Arizona "alleges that it did not have knowledge," (The State of Arizona's Opposition to Defendants AstraZeneca Pharmaceuticals LP and Zeneca Inc.'s Motion to Dismiss Zoladex ("Pl. Opp.") at 4), it is premature to address the implausibility of its claims. Such a position reflects a fundamental misunderstanding of Rule 12(b)(6) after *Bell Atlantic Corp. v. Twombly*, 550 U.S., 544, 127 S. Ct. 1955 (2007) and cannot stand. As set forth in AstraZeneca's opening memorandum and in Defendants' memoranda (in which AstraZeneca joins), the Complaint should be dismissed in its entirety. At a minimum, all claims against AstraZeneca relating to payments for Zoladex should be dismissed.

ARGUMENT

I. Plaintiff's Zoladex Claims Must Be Dismissed from at Least 2001

Plaintiffs' claims fail to meet the pleading standard articulated in *Bell Atlantic Corp. v*. *Twombly*, 550 U.S. 544, 127 S. Ct. 1955 (2007) and should be dismissed accordingly. *Twombly* requires that a plaintiff must allege a "plausible entitlement to relief" to survive a motion to dismiss. 127 S. Ct. at 1967; *New England Carpenters Health Benefits Fund v. McKesson Corp.*, 573 F. Supp. 2d 431, 433 (D. Mass. 2008) (Saris, J.)). As this Court has recognized, courts are

"free to disregard 'bald assertions, unsupportable conclusions, and opprobrious epithets." *Id.* at 433 (quoting *In re Citigroup*, *Inc.*, 535 F.3d 45, 52 (1st Cir. 2008)).

Plaintiff's conclusory assertion that the question of plausibility "requires a fact-driven inquiry inappropriate at the motion to dismiss stage," (Pl. Opp. at 6) runs directly counter to the policies underlying *Twombly*, which are aimed at preventing "a largely groundless claim" from "tak[ing] up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." *Twombly*, 127 S. Ct. at 1966 (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005) (internal citation omitted)). Indeed, AstraZeneca seeks not a "fact-driven inquiry" but rather, in accordance with *Twombly*, "enough facts to state a claim to relief that is plausible on its face." *See id.* at 1974.

Rather than explaining the supposed "plausibility" of its claim - which it cannot - Plaintiff attempts to deflect attention from its pleading inadequacies by targeting AstraZeneca's supposedly improper invocation of materials beyond the Complaint. (*See* Pl. Opp. at 6.) Even accepting as true Plaintiff's contention that it successfully pleaded around the 2003 Settlement, it is well established that a court may take judicial notice of publicly available materials, including the 2003 Settlement and the 2001 Complaint in the MDL Proceeding. Those documents demonstrate on their face that Plaintiff's claim that it did not know of the alleged "fraud" with respect to Zoladex is utterly implausible, at least from 2001 forward.

Nonetheless, Plaintiff argues that even if this Court could consider publicly available materials, they do not demonstrate that Plaintiff knew about the alleged AWP "scheme." For example, Plaintiff argues that it lacked knowledge of the 2001 lawsuit because the "perfect storm" settled only over "certain federal government entities" (Pl. Opp. at 2). Plaintiff neglects

¹ See Diva's, Inc. v. City of Bangor, 411 F.3d 30, 38 (1st Cir. 2005) (settlement agreement properly considered); Alternative Energy, Inc. v. St Paul Fire & Marine Ins. Co., 267 F.3d 30, 33–34 (1st Cir. 2001) (same).

to mention that Arizona payors were included in the 2001 putative class and, indeed, brought another putative class action in Arizona state court in 2002.² It defies logic that a lawsuit was filed on behalf of Arizona payors based on the same AWP allegations in 2001, but the State had *no knowledge* of the alleged scheme. In another misguided attempt to sidestep dismissal, Plaintiff argues that the 2003 Settlement related to conduct concerning "Arizona Medicaid only." (*Id.* at 3.) To the contrary, the 2003 Settlement clearly described the manner in which the State believed AstraZeneca had improperly engaged in a "scheme" to inflate AWP, "knowing it was used by Medicaid *and others* for drug reimbursement." (2003 Settlement pmbl. ¶ F(iii) (emphasis added).)

At its core, Plaintiff's assertion that "it knew nothing" about the alleged AWP scheme (Pl. Opp. at 6) is completely unsupportable. These claims are implausible against the backdrop of more than seven years of AWP-related litigation attacking the alleged AWP "scheme," including settled and/or adjudicated claims brought by many of the very same Arizona private citizens and third-party payors ("TPPs") (filed by the same counsel) on whose behalf Plaintiff now brings this action, not to mention the wealth of publicly available information regarding the difference between AWP and actual acquisition costs. Accordingly, all Zoladex claims from at least 2001 forward should be dismissed for failure to satisfy Rule 12(b)(6).

II. Plaintiff's Action Is Barred by the Statute of Limitations

Although Plaintiff claims that it should enjoy the benefits of the exception to the statute of limitations because it purports to bring this lawsuit in an enforcement capacity (Pl. Opp. at 5), where as here, the State asserts a claim that "belongs only to . . . some small and distinct section

² The background concerning the 2001 Complaint and the 2003 Settlement Agreement is outlined in AstraZeneca's opening memorandum. In addition, on March 15, 2002, a putative class action, *Swanston v. TAP Pharmaceutical Products*, No. CV 2002-004988 (Super. Ct. Ariz.), was filed in Arizona state court, purporting to assert claims on behalf of persons and entities in Arizona and the United States for alleged consumer protection act violations relating to "inflated" AWPs. The *Swanston* complaint also included specific allegations about Zoladex.

of the public," the exception does not apply. *Trimble v. Am. Sav. Life. Ins. Co.*, 733 P.2d 1131, 1139 (Ariz. Ct. App. 1986); *Diamond Benefits Life Ins. Co. v. Resolute Holdings*, 907 P.2d 63 (Ariz. 1995) (following *Trimble*). For the reasons below and those discussed in Defendants' joint reply, stripped to its core, this case is nothing more than a private class action where the State is a nominal party without any cognizable quasi-sovereign interest.

First, the State's interest is minimal because these private citizens and TPPs on whose behalf Plaintiff brings this action have already brought their own litigation. In particular, many of the private payors associated with this lawsuit not only have adequate protection from parallel litigation in the MDL and *Swanston* actions, but have already settled their claims relating to Zoladex with AstraZeneca. Plaintiff concedes as much in its opposition, arguing only that the overlapping restitution/disgorgement claims for consumers could not yet be dismissed because the Zoladex settlement was not final. (Pl. Opp. at 16.) However, since the opposition was filed, the Zoladex settlement has been finally approved, rendering dismissal of these overlapping claims for consumers appropriate, as Plaintiff cannot recover damages for private consumers who have already settled their claims. (Zoladex Settlement, Docket No. 5802 (Dec. 19, 2008).)

Second, Plaintiff is bringing this action on behalf of sophisticated, business-savvy entities, distinguishing this case from the paradigmatic *parens patriae* action brought on behalf of citizens suffering from discriminatory sales practices. Not surprisingly, no published case brought by the Arizona Attorney General under the Arizona Consumer Fraud Act mirrors the one brought here on behalf of sophisticated TPPs.

Third, to the extent that Plaintiff seeks to characterize this case as an "enforcement" action by seeking injunctive relief (*see* Pl. Opp. at 5), such an attempt fails under Arizona law, where "the issue of injunctive relief is moot when the 'events make it absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *SAL Leasing, Inc. v.*

State ex rel. Napolitano, 10 P.3d 1221, 1229 (Ariz. Ct. App. 2000) (quoting State ex rel. Babbitt v. Goodyear Tire & Rubber Co., 626 P.2d 1115, 1118 (Ariz. 1981)). Plaintiff fails adequately to allege what conduct it seeks to enjoin, instead referencing a broad spectrum of "wrongful conduct" upon which all of its claims are predicated. (See, e.g., Compl. ¶ 520.) To the extent that Plaintiff's claim for injunctive relief is premised on publication of AWPs for any AstraZeneca product (including Zoladex), AstraZeneca has not only provided Average Sales Prices ("ASPs") for Zoladex, but no longer reports AWPs for any of its products.

To the extent that Plaintiff's claim for injunctive relief is premised on some other aspect of AstraZeneca's conduct, Plaintiff has failed sufficiently to apprise AstraZeneca of the content of that conduct and therefore cannot satisfy the pleading standards under Rule 12(b)(6). In any event, Plaintiff has failed to explain (nor can it) how it may evade this Court's prior holdings that claims for injunctive relief are mooted after the passage of the MMA. *See In re Avg. Pharm. Indus. Wholesale Price Litig.*, 252 F.R.D. 83, 106 (D. Mass. 2008); *In re Avg. Pharm. Indus Wholesale Price Litig.*, 491 F. Supp. 2d 20, 44 (2007); Pl. Opp. at 3 (acknowledging prior holding); *see also First Databank* Hr'g Tr. at 55-56. Plaintiff's injunctive relief claims should be dismissed as moot, further undercutting Plaintiff's claim that this is an "enforcement" action.³

CONCLUSION

For the reasons set forth in Defendants' Reply Memorandum of Law, the Complaint should be dismissed as to AstraZeneca. If the Complaint is not dismissed in its entirety as to all defendants, for the reasons set forth above, AstraZeneca respectfully requests that the Court dismiss Zoladex claims brought by the State of Arizona.

³ Plaintiff's claims for civil penalties must be dismissed for the same reasons that Plaintiff's claims for injunctive relief must be dismissed. The rationale for civil penalties under the Arizona Consumer Fraud Act is deterrence. *See State ex rel. Woods v. Sgrillo*, 859 P.2d 771, 772 (Ariz. Ct. App. 1993); *State ex rel. Corbin v. United Energy Corp. of Am.*, 725 P.2d 752 (Ariz. Ct. App. 1986). Where, as here, the allegedly wrongful conduct has ceased, there is no basis for civil penalties.

Dated: Boston, Massachusetts

January 15, 2009

Respectfully Submitted,

By: /s/ Katherine B. Schmeckpeper

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered on January 15, 2009 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: <u>/s/ Katherine B. Schmeckpeper</u>
Katherine B. Schmeckpeper